

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PI0305339-3		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/BR 2004/000235	International filing date (day/month/year) 25 November 2004 (25.11.2004)	Priority Date (day/month/year) 28 November 2003 (28.11.2003)	
International Patent Classification (IPC) or national classification and IPC IPC⁸: A61K 31/52 (2006.01); B32B 27/32 (2006.01); B32B 27/36 (2006.01); A61J 1/00 (2006.01)			
Applicant HALEX ISTAR INDUSTRIA FARMACEUTICAS LTDA.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examination Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>3</u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I. <input checked="" type="checkbox"/> Basis of the opinion II. <input type="checkbox"/> Priority III. <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV. <input type="checkbox"/> Lack of unity of invention V. <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI. <input type="checkbox"/> Certain documents cited VII. <input checked="" type="checkbox"/> Certain defects in the international application VIII. <input type="checkbox"/> Certain observations on the international application 			
Date of submission of the demand 5 October 2005 (05.10.2005)		Date of completion of this report 23 May 2006 (23.05.2006)	
Name and mailing address of the IPEA/AT Austrian Patent Office Dresdner Straße 87 A-1200 Vienna Facsimile No. 1/53424/200		Authorized officer KRENN M. Telephone No. 1/53424/435	

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/BR 2004/000235

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
pages 1-29, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☒ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement) under Article 19
pages _____, filed with the demand
pages 33-35, filed with the letter of 3 May 2006 (03.05.2006).
- ☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____.
- ☐ the claims, Nos. _____.
- ☐ the drawings, sheets/fig _____.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as „originally filed“ and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/BR 2004/000235**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)

Claims 1-9

YES

Claims ----

NO

Inventive step (IS)

Claims 1-9

YES

Claims ----

NO

Industrial applicability (IA) Claims 1-9

YES

Claims ----

NO

Citations and explanations (Rule 70.7)

None of the documents cited the Search Report discloses a process for making ganciclovir crystals free of alkaline residues; thus claims 1-4 are new as well as inventive.
Both trilayered packing material composed of polyester/polyethylene/propylene copolymer and ready-for-use formulations using said packing material (claims 5-9) are new as well as inventive.

Industrial applicability is given for claims 1-9.

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

In a solution crystals are normally solved; thus a solution cannot contain crystals prepared according to a particular process. Consequently, the formulations "...crystals from active principle.." and "...prepared according to process of claim 1.." should be deleted in claim 5.